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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
24,111	03/26/79	Yasuhide Tachi, et al	A13132P1

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EXAMINER	
Roberts	
ART UNIT	PAPER NUMBER
125	5

DATE MAILED: MAILED

JUN 28 1979

GROUP 120

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined. ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited, Form PTO-892.
2. ☐ Notice of Informal Patent Drawing, PTO-948.
3. ☐ Notice of Informal Patent Application, Form PTO-152.
4. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1 and 2 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1 and 2 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ The formal drawings filed on _____ are acceptable.

8. ☐ The drawing correction request filed on _____ has been ☐ approved. ☐ disapproved.

9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has
   ☐ been received. ☐ not been received. ☐ been filed in parent application, serial no. _____,
   filed on _____.

10. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

11. ☐ Other

The claims in the case are 1 and 2.

Claims 1 and 2 are rejected under 35 USC 103 as being obvious from the disclosure of Ercoli et al in combination with Elks et al and Shapiro et al. The primary reference discloses hydrocortisone and the acylates thereof. The secondary references disclose the process for making 17 -mono esters and 17.21 di-esters of anti-inflammatory steroids and the fact that the new esters have an anti-inflammatory action on topical activity far superior to the unacylated compounds. In addition, to the high anti-inflammatory action, it was found that there was little risk of disturbance of the mineral balance and other systemic action should the diesters be absorbed.

The preparation of the 17.21-diesters (having similar or dissimilar acyl moieties) may be prepared through a 17.21-ortho ester intermediate. In this method the 17.21-diol is treated with a lower alkyl ester of an ortho carboxylic acid in the presence of a strong acid catalyst to form the corresponding 17.21 ortho ester which upon mild acid hydrolysis is converted to the corresponding 17-mono ester. It is further taught that the introduction of an ester function at C-21 which may either be the same as or different from the ester function at C-17 is readily accomplished by standard acylation procedures.

In view of the teaching of the secondary references relating to the preparation and therapeutic importance of anti-inflammatory 17.21-steroidal diacylates, it is the examiner's position that the diacylate derivatives of Ercoli et al's compounds, as recited in claim I would be obvious to one of ordinary skill in the art. The particular acylate combination is of no patentable significance since the esters represent nothing more than a matter of choice. With respect to claim 2, it is the examiner's position that one of ordinary skill in the art, upon contemplating the nature of the subject matter shown in the disclosure of the prior art, in view of his knowledge that closely related steroid compounds have been combined with pharmaceutically acceptable carriers in a manner similar to that here and administered to treat inflammatory conditions, would find adequate suggestion of the subject matter as a whole which is claimed.

No claims are allowed.

Elbert L. Roberts
Primary Examiner
Art Unit 125

Roberts/tmw
A/C 703
557-2575